IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



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| In re application of: Bill H. McAnalley, et al. | § | Attorney Docket No. 23100.36 |
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| | § | Confirmation No. 9780 |
| Serial No.: 09/242,215 | § | |
| | § | Customer No. 27683 |
| Filed: February 8, 1999 | § | |
| | § | Group Art Unit: 1654 |
| For: COMPOSITIONS OF PLANT CARBOHYDRATES AS DIETARY SUPPLEMENTS | § | Examiner: M. Flood |
| | § | |

## DECLARATION UNDER RULE 37 C.F.R. § 1.132

1. My name is Stephen Boyd. I am the Medical Director and Administrator of the Department of Health Sciences, Mannatech, Inc., Coppell, Texas. I received a B.S. in 1962 and a Ph.D. in 1965, both from the Department of Chemistry of the University of Glasgow, Scotland. I was awarded a Post-Doctoral Research Fellowship in 1965 from the Department of Chemistry of the State University of New York at Buffalo, Buffalo, New York. I received an M.D. from the Department of Medicine of the University of Toronto in 1972. In 1998 I received Board Certification from the American Academy of Wound Management. I was elected a Fellow of the Royal Society of Medicine, U.K., in 2001.

2. Since 1975 I have worked continually in the field of clinical medicine and medical research.

3. Since 1992 I have worked continually in the field of carbohydrates in an effort to research and develop naturally occurring carbohydrates as therapeutics and nutritional supplements.

4. I have authored publications and given numerous presentations that are detailed in my Curriculum Vitae, a copy of which is attached.

5. My research interests include the biochemistry, biology, pharmacology and clinical application of carbohydrates.

6. I have read and understand U.S. Patent Application Serial No. 09/242,215 to McAnalley et al. (the "McAnalley Application"), U.S. Patent No. 4,871,557 to Linscott ("Linscott"), U.S. Patent No. 5,021,560 to Montreuil et al. ("Montreuil"), "Analysis of the Isolated Hyaline Layer of Sea Urchin Embryos", Developmental Biology 27, 494-503 (1972) by Citkowitz ("Citkowitz") and U.S. Patent No. 3,947,601 to Ortega ("Ortega").

7. I believe that claims 1, 6-17, 22, 27-36 and 40-43 of the McAnalley Application are directed to an important and patentable improvement over the subject matter described in Linscott, Montreuil, Citkowitz and Ortega.

8. I have reviewed the Office Action from the United States Patent and Trademark Office dated December 18, 2002, in the McAnalley Application. I noted the following statement on page 4, lines 9-12 of the Office Action:

> "[N]owhere in the disclosure of Applicant can be found any teaching or suggestion of a treatment of sources of carbohydrates comprising the claimed saccharides to make the saccharides of the claimed invention bioavailable as monosaccharides."

9. Contrary to this statement, the McAnalley Application discloses at page 8, lines 19-23 that in an embodiment of the invention disclosed in the McAnalley Application, the compositions:

> "[I]nclude predigested forms of at least one of the eleven essential carbohydrates. This can include one or all of the following: 1) physical digestion such as shearing or treatment with ultrasound, 2) chemical digestion such as enzymatic digestion, and acid or base hydrolysis, and 3) biological digestion with microbes such as bacteria, fungi or molds."

10. Based on my experience with carbohydrate chemistry, the predigestion of carbohydrates such as tragacanth gum and gum ghatti makes the constituent saccharides of such gums bioavailable as monosaccharides. Accordingly, one skilled in the art would have understood that the predigestion of sources of carbohydrates comprising the claimed saccharides would make the saccharides of the claimed invention bioavailable as monosaccharides.

11. In the same Office Action I note the following statement therein:

> "Applicant expressly discloses dietary supplement compositions comprising the same constituent ingredients as disclosed by Linscott, e.g. gum ghatti and gum tragacanth;

and, thus the dietary supplement compositions taught by Linscott, which comprise the instantly claimed saccharides inherently must read upon such bioavailable monosaccharides." (Page 7, lines 9-12).

12. This statement is incorrect in view of the state of the dietary supplementart as of August 4, 1997. One skilled in the art would *not* have concluded that the Linscott patent anticipated the claims of the McAnalley Application for the following reasons:

First, the Linscott patent relates to a granola bar with supplemental dietary fiber that overcomes the taste and texture objections associated with high fiber content in a granola bar. Since 1976 dietary fiber by definition (AOAC monograph "Dietary Fiber Analysis and Application" 1997, page 2, by S. Cho et al, Copyright AOAC INTERNATIONAL, containing the relevant reference, Trowell HC, et al, Lancet 1976;1:967, attached as Exhibit A) includes all indigestible polysaccharides such as gums, modified cellulose, mucilages, oligosaccharides, and pectins. To quantitate dietary fiber in food, current US Food Labeling Regulations defer to the officially accepted methodology of the AOAC International. The Official Methods of Analysis, 16th Ed. 1995, AOAC INTERNATIONAL, Gaithersburg, MD, attached as Exhibit B. Methods 985.29 and 991.43 are based on the definition of dietary fiber as "the polysaccharides and remnants of plant material that are resistant to hydrolysis (digestion) by human alimentary enzymes". In other words, dietary fibers are polysaccharides that, by definition, must consist of covalently linked monosaccharides. Since they are, by definition, non-digestible, they cannot be a nutritional source of these same monosaccharides and, therefore, would not have been considered by those of ordinary skill in the art as a dietary supplement providing these same sugars.

Second, it is not relevant to me that dietary fibers contain sugars. What is relevant to me is that these sugars cannot be digested in the human gastrointestinal tract. In order to be a nutritional source of the constituent sugars, dietary fibers would have to be pre-treated in some way to enable digestion and absorption to take place. Pre-treatment of such dietary fibers is not disclosed or suggested in the Linscott patent. Pre-digestion, however, is addressed in the McAnalley Application, specifically, at page 8, lines 19-23 which discloses that:

"In another embodiment of the present invention, the compositions include predigested forms of at least one of the eleven essential carbohydrates. This can include one or all of the following: 1) physical digestion such as shearing or treatment with ultrasound, 2)

chemical digestion such as enzymatic digestion, and acid or base hydrolysis, and 3) biological digestion with microbes such as bacteria, fungi or molds."

Absent a pre-treatment step such as pre-digestion according to the McAnalley Application, the compositions disclosed by Linscott do not include bioavailable monosaccharides.

13. In the same Office Action I note the following statements therein:

"Claims 1 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Montreuil et al."

"[T]he instantly claimed invention does not require that a glycoprotein be treated in a manner to make bioavailable the constituent saccharides of the glycoprotein. Moreover, there is no indication that the constituent saccharides of the glycoprotein taught by Montreuil are not bioavailable as monosaccharides. Furthermore, Applicant has not provided a clear and convincing argument that the constituent saccharides of the glycoprotein taught by Montreuil are not bioavailable as monosaccharides."

14. These statements are incorrect in view of the state of the dietary supplement art as of Aug 4, 1997. One skilled in the art would not have concluded that the Montreuil patent anticipated the claims of the McAnalley Application for the following reasons:

The Montreuil patent relates to a polymeric glycoprotein that is an immunizing agent against shistosomiasis, a parasitic disease, and the determination of its structure in order to enable its synthesis to be carried out. The glycoproteins disclosed by Montreuil are structurally different from the compositions claimed in the McAnalley Application. Specifically, the glycoproteins disclosed in Montreuil are extracted from another organism and consist of multiple covalently linked sugars and proteins. The glycoproteins contain alpha and beta linked sugar bonds. The human gut cannot digest molecules having beta covalent sugar bonds, such as cellulose (Guyton & Hall, Textbook of Medical Physiology, 10$^{th}$ edition, 2000, pages 754-756, attached as Exhibit C) and, in my opinion, such molecules are not a nutritional source of the constituent sugars. The Montreuil patent does not disclose that the glycoproteins are a nutritional source of these sugars nor is there anything in the Montreuil patent to suggest that the glycoproteins could function in any remote way as a dietary supplement. In fact, in order for the compositions disclosed in the Montreuil patent to function as immunizing agents and be recognized as antigens their structures would have to remain intact in biological systems and

not degrade into their component sugars. While all glycoproteins, by definition, contain sugar molecules, not all glycoproteins can be a source of sugars as nutrients. Pre-digestion may be necessary for some sugar containing compounds to enable them to function as dietary supplements providing sugars.

Contrary to the compositions claimed in the McAnalley Application, pre-digestion of glycoproteins is not disclosed or suggested in the Montreuil patent. Absent a pre-digestion step, the constituent saccharides of the glycoprotein taught by Montreuil would not be bioavailable as monosaccharides.

15. In the same Office Action I note the following statements therein:

> "Claim 40 is rejected under 35 U.S.C. 102(b) as being anticipated by Citkowitz or Ortega."
>
> "As there is no indication that the constituent saccharides of the referenced compositions taught by Citkowitz and Ortega are not bioavailable as monosaccharides and as Applicant has not provided a clear and convincing evidence to suggest otherwise, both of the cited references are deemed to anticipate the claimed subject matter."

16. These statements are incorrect in view of the state of the dietary supplement art as of Aug 4, 1997 for the following reasons:

One skilled in the art would not have concluded that the Ortega patent anticipated the claims of the McAnalley Application. Specifically, the Ortega patent relates to a food for sea creatures that can be accommodated by the ecological system of a salt water aquarium environment to provide a food for both vertebrates and invertebrates that can be dispersed in the water as a visible cloud with minimal settling on the aquarium bottom. According to the Ortega patent, this is accomplished by pulverizing sea urchin eggs into a uniform mass, preserving the homogenizate and mixing it with water. In other words, Ortega relates to the physical characteristics of a total food for sea creatures. It relates to the dispersibility, visibility and settling of the food not to the nutritional content, specifically not to the nutritional carbohydrate content of the food. The food according to Ortega is prepared from living organisms. The bodies of all living organisms contain carbohydrates. To so state is obvious to anyone trained in the life sciences. The carbohydrates are covalently linked to proteins and lipids as glycoproteins and glycolipids. However, the fact that sea urchin eggs contain

carbohydrates does not necessarily make them nutritional supplements by which such carbohydrates are provided. Ortega discloses a whole food for sea creatures with certain physical characteristics and not, in my opinion, a dietary supplement, specifically not a dietary supplement that provides carbohydrates.

It is nowhere disclosed or suggested in Ortega that the sea urchin eggs be pre-digested to facilitate carbohydrate digestion and absorption in humans. The composition of claim 40 of the McAnalley Application includes predigested forms of at least one of the eleven monosaccharides.

Citkowitz refers to the chemical analysis of the hyaline layer of sea urchin embryos. Specifically, the carbohydrates are assayed using gas-liquid chromatography and the thiobarbituric acid method. As stated above, the sea urchin egg is a living organismand would be expected to contain carbohydrates covalently bound to proteins and lipids. The fact that the hyaline layer of a sea urchin embryo can be assayed for carbohydrates by standard laboratory chemical analytical techniques does not necessarily lead to the assumption that the same carbohydrates would be available as dietary supplements within the human body.

Furthermore, as stated in the Citkowitz paper and in Table 1 on page 496 thereof, analysis of the sea urchin hyaline layer documented that it was approximately 97% protein and only 2-3% carbohydrate. The carbohydrates listed in Table 1 are present at rates of approximately 5-40 nmoles/mg protein. The hyaline layer of the sea urchin embryos would be expected to constitute a small fraction of the whole egg. Therefore, the amount of the named carbohydrates that could theoretically be obtained from a sea urchin egg, on the basis of this analysis, would be extremely small, and probably negligible as a potential dietary supplement source of carbohydrates.

In addition, Citkowitz provides no evidence that the hyaline layer of the sea urchin embryo containing the covalently bound named carbohydrates could function as a dietary supplement source for the same carbohydrates nor does it address the issue of pre-digestion of the hyaline layer to facilitate carbohydrate digestion and absorption in humans.

Accordingly, the constituent saccharides of the referenced compositions taught by Citkowitz and Ortega are not bioavailable as monosaccharides.

17. Accordingly, I do not believe that any of Linscott, Montreuil, Citkowitz and Ortega, alone or in combination, discloses or suggests the compositions of claims 1, 6-17, 22, 27-36 and 40-43 of the McAnalley Application since none of them disclose or suggest that their compositions are structurally the same as those in the McAnalley Application, provide saccharides as dietary supplements as claimed in the McAnalley Application or address the issue of pre-digestion to facilitate human absorption of saccharides as addressed in the McAnalley Application.

I acknowledge that willful false statements are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and may jeopardize the validity of this application or any patent issuing from it. I declare under penalty of perjury under the laws of the United States that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true.

Stephen Boyd

Stephen Boyd

April 14, 2003

Date

D-1121549.1

**Stephen Boyd, BS, MD, PhD, FRSM**
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**Tyler, TX 75703**
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## EDUCATION / PROFESSIONAL:

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| 2001 | Elected Fellow of the Royal Society of Medicine, London, UK |
| 1998 | Diplomate of the American Academy of Wound Management |
| 1974-75 | Family Practice, Toronto General Hospital<br>▪ Included Family Practice, Medicine, Surgery, Plastic Surgery, Emergency Medicine and Pediatrics |
| 1970-74 | M.D., University of Toronto |
| 1965-66 | Post-Doctoral Research Fellowship, State University of New York<br>▪ Thermodynamics of Ion Association Publication, J Chem Eng Data, 1967;**12**:601 |
| 1962-65 | Ph.D. University of Glasgow<br>▪ Thermodynamics of Ion Association Publication, J Chem Soc. **1965**, p. 7353 |
| 1958-62 | B.S. Chemistry (Honors), University of Glasgow<br>▪ Organic, Inorganic and Physical Chemistry |

## EMPLOYMENT:

1997-Present **Medical Director and Administrator**
Department of Health Sciences
Mannatech Inc., Coppell, Texas

Manage the clinical research program investigating impact of nutrition and nutritional supplementation in health and disease.

Responsibilities included:

- Design and implementation of basic scientific and clinical trials
- Correlation of biomarkers of health and disease with clinical outcomes
- Product safety monitoring program

Provide medical, scientific and technical support for product marketing.

Responsibilities included:

- Strategic planning and business development
- Education and training
- Market support, presentations, literature

1992-1997 **Medical Director**
Carrington Laboratories, Inc.
Irving, Texas

Manage the clinical research program in Cancer, Ulcerative Colitis, Wound and Skin Care, emphasis on Immunology.

Responsibilities include:

- Design and implementation of pre-clinical and clinical trials
- Supervision of Clinical Research Associates
- Data management and regulatory agency submissions

Provide medical, scientific and technical support to Sales and Marketing

Responsibilities included:

- Strategic planning and business development
- Sales education and training
- Market support, conferences, focus groups, customer interaction, literature
- New product development and acquisition. New product patent granted.

1980-92 **Medical Practice**
Tyler, Texas

General and Family Practice including:

- Preventive medicine and wellness
- Smoking cessation seminars
- Supervisor, hospital outpatient cardiac rehabilitation and monitoring
- Participated in Phase IV clinical trials, focus groups and teleconferences

1978-80 **Medical Director of Research**
Ortho Pharmaceuticals Inc.
Toronto, Canada

Managed the clinical research program for Canada.

Responsibilities included:

- Design and implementation of Phase III and IV trials in contraception, immune modulation, GI and GU disorders
- Provided medical, scientific and technical support to Sales and Marketing
- Prepared a monograph for Canadian Government

1975-78 **Medical Practice**
Oakville, Ontario, Canada

General and Family Practice including:
- Obstetrics, surgery and pediatrics

1966-70 **Senior Research Chemist**
Dunlop Research Center
Mississauga Ontario, Canada

Department Head, Emulsion Polymer Research and Analytical Services

Responsibilities included:

- New product and process development
- Developed high pressure process for polymer synthesis
- Development of analytical program to support polymer research

**PROFESSIONAL ASSOCIATIONS:**

Texas Academy of Family Physicians
President and Program Chairman - local chapter
American Academy of Family Physicians
American Medical Association
American Academy of Wound Management
Royal Society of Medicine

## PRESENTATIONS:

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| 10/14/92 | Acemannan, an Anti-viral Immune Modulator<br>University of Texas<br>Arlington, Texas |
| 10/26/93 | Mechanism and Phases of Wound Healing<br>Northwest Regional Primary Care Association<br>Seattle, Washington |
| 11/15/93 | The Challenge of Wound Care Management in the 90's<br>Stanford University<br>Palo Alto, California |
| 06/28/94 | Wound Healing and Immune Mechanisms in Tissue Repair<br>New Concepts in Wound Care Management<br>Douglas Community Hospital, Oregon |
| 11/18/94 | Anatomy and Physiology of Wound Repair<br>Wound Management in the 21st Century<br>Kaiser Permanente<br>Portland, Oregon |
| 06/01/95 | Wound Management in the 90's<br>Oregon State Enterostomal Therapist Conference<br>Portland, Oregon |
| 09/08/95 | Treatment of Radiation Skin Reactions<br>Southern California Permanente Medical Group |
| 09/15/95 | Anatomy and Physiology of Wound Repair<br>University of California<br>Davis, California |
| 10/15/95 | Mechanisms of Wound Repair<br>WOCN (Wound Ostomy Continence Nurses Society)<br>Pacific Coast Region - Annual Meeting<br>Honolulu, Hawaii |
| 04/03/96 | Mechanisms of Wound Repair<br>Goldwater Memorial Hospital<br>New York, New York |
| 04/05/96 | Wound Care<br>Nursing Grand Rounds, New York Methodist Hospital<br>Brooklyn, New York |
| 05/08/96 | Mechanisms of Wound Repair<br>Evolving Practices in Wound Management<br>Portland, Oregon |

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| 05/17/96 | Advances in Wound Care<br>Colorado WOCN<br>Boulder, Colorado |
| 06/11/96 | Wound Care Update<br>Rose State College<br>Oklahoma City, Oklahoma |
| 08/29/96 | Management of Radiation Skin Injury<br>UCLA Department of Radiation Oncology<br>Los Angeles, California |
| 10/11/96 | Plant Derived Drugs<br>Northwest Region WOCN Symposium<br>Coeur D'Alene, Idaho |
| 10/24/96 | Anatomy and Physiology of Wound Repair<br>Grand Rounds, Emory University Department of Surgery<br>Atlanta, Georgia |
| 10/26/96 | Anatomy and Physiology of Wound Repair<br>Diabetes Complications<br>American Diabetes Association<br>Orlando, Florida |
| 09/11/97 | Anatomy and Physiology of Wound Repair<br>International Aloe Science Council<br>Irving, Texas |
| 01/09/98 | Nutritional Supplementation in Health and Disease<br>United Pharmacists Drug Board<br>Phoenix, Arizona |
| 01/17/98 | Healthcare Professional Presentation<br>Nutrition and Health<br>Lansing, Michigan |
| 04/17/98 | Contemporary Medicine and Nutritional Supplementation<br>Grand Rounds, University of Arkansas<br>Little Rock, Arkansas |
| 04/30/98 | Healthcare Professional Presentation<br>Contemporary Medicine and Nutritional Supplementation<br>Kelwona, British Columbia, Canada |
| 06/12/98 | Contemporary Medicine and Nutritional Supplementation<br>Washington State Pharmacists Association<br>Yakima, Washington |

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| 07/23/98 | Healthcare Professional Presentation<br>Nutritional Supplementation in Health and Disease<br>Tyler, Texas |
| 08/19/98 | Nutritional Supplementation in Health and Disease<br>West Texas Pharmacists Association<br>Lubbock, Texas |
| 10/02/98 | Glyconutritional Supplementation<br>Australian Society for Experimental Pathology<br>Sydney, Australia |
| 02/18/99 | Glyconutritional Supplementation<br>Grand Rounds, St. Thomas Hospital<br>St. Thomas, US Virgin Islands |
| 07/04/99 | Healthcare Professional Presentation<br>Nutritional Supplementation and Health<br>London, Ontario, Canada |
| 11/16/99 | Healthcare Professional Presentation<br>Glyconutritional Supplementation<br>London, United Kingdom |
| 11/20/99 | Healthcare Professional Presentation<br>Glyconutritional Supplementation<br>Manchester, United Kingdom |
| 11/23/99 | Healthcare Professional Presentation<br>Glyconutritional Supplementation<br>Edinburgh, United Kingdom |
| 12/18/99 | Healthcare Professional Presentation<br>Glyconutritional Supplementation<br>Duncan, Oklahoma |
| 01/12/00 | The Growing Market for Nutraceuticals<br>Nutraceuticals and Functional Foods Conference<br>London, United Kingdom |
| 09/09/00 | So! You Think You Are Healthy?<br>Bexar County Pharmacy Association<br>San Antonio, Texas |
| 10/28/00 | Nutritional Supplementation in Health and Disease<br>Healthcare Professional Conference<br>Osaka, Japan |
| 02/01/01 | Nutritional Supplementation in Health and Disease<br>Health Professional Seminar<br>Loma Linda Hospital, CA |

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| 03/09-10/01 | Anti-Aging and Nutrition<br>Better Living Home Show<br>Burlington, Ontario, Canada |
| 10/24/01 | Nutrition and Health<br>BCTV News Broadcast<br>Sault St. Marie, Ontario, Canada |
| 10/26/01 | Nutritional Supplementation in Health and Disease<br>Healthcare Professional Seminar<br>Sudbury, Ontario, Canada |
| 1/18/02 | Glycobiology<br>Staff CME Meeting<br>Grant Hospital, Chicago, IL |
| 1/22/02 | Nutritional Supplementation in Health and Disease<br>Healthcare Professional Seminar<br>Plymouth, UK |
| 1/23/02 | Trends in Healthy Ingredients<br>Nutraceuticals and Functional Foods Conference<br>London, UK |
| 2/4/02 | Glycobiology, The New Frontier<br>The Institute of Integrative Medicine<br>London, Ontario |
| 3/6/02 | Nutrition and Health<br>Healthcare Professional Conference Call<br>UK, Dr. Peter Smith |
| 3/21/02 | Glyconutritional Supplementation<br>Live radio Interview/presentation<br>Dr. Michael Klapper, HI |
| 4/12/02 | Glycobiology, The New Frontier<br>Healthcare Professional Seminar<br>Dallas, TX |
| 4/14/02 | Introduction to Glycobiology<br>Proevity CME Seminar, AMA Category 1<br>Dallas, TX |
| 4/22/02 | Glycobiology, The New Frontier<br>Staff Meeting<br>Union Hospital, Moose Jaw, SK |
| 4/23/02 | Glycobiology, The New Frontier<br>Staff Presentation<br>Wascana Rehab. Hospital, Regina, SK |

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| 4/27/02 | Glycobiology, The New Frontier<br>Victoria Pharmacists' Association<br>Victoria, BC |
| 5/11/02 | Glycobiology, The New Frontier in Medical research<br>Proevity CME Seminar, AMA Category 1<br>Wilmington, DE |
| 5/28/02 | Complementary and Alternative Medicine<br>Texas House of Representatives Committee<br>Austin, TX |
| 6/23/02 | Glycobiology, The New Frontier in Medical Research<br>Proevity CME Seminar, AMA Category 1<br>Ft. Lauderdale, FL |
| 6/26/02 | Glycobiology, The New Frontier in Medical Research<br>Staff Presentation<br>Welland Hospital, Welland, ON |
| 6/27/02 | Glycobiology, The New Frontier in Medical Research<br>Staff Presentation<br>Ottawa General Hospital, Ottawa, ON |
| 7/19/02 | Glycobiology, The New Frontier in Medical Research<br>Healthcare Professional Seminar<br>Mississauga, ON |
| 8/7/02 | Glyconutritional Supplementation, Research Potential<br>University of Utah<br>Salt Lake City, UT |
| 9/16/02 | Clinical Efficacy of Glyconutritional Supplementation<br>6th Jenner Glycobiology and Medicine Symposium<br>Seillac, France |
| 12/13/02 | Glycobiology, The New Frontier in Medicine<br>Healthcare Professional Seminar<br>Toronto, ON |
| 1/15/03 | Neutraceuticals, Trends in the Market<br>Neutraceuticals, Functional Foods & Probiotics Conf.<br>London, UK |
| 3/22/03 | *In Vivo* Determination of Biomarkers of Oxidative Stress<br>Poster presentation<br>American Chemical Society National Meeting<br>New Orleans, LA |

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| 4/5/03 | Glyconutritional Supplementation<br>12th International LIFExpo on Integrative Medicine<br>Cleveland, OH |
| 4/6/03 | Glycobiology & Medicine<br>12th International LIFExpo on Integrative Medicine<br>Cleveland, OH |